# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants: Campbell Rogers, Elazer R. Edelman, and Daniel I. Simon

Serial No.: 08/823,999 Art Unit: 1644

Filed: March 25, 1997 Examiner: Phillip Gambel

For: *MODULATION OF VASCULAR HEALING BY INHIBITION OF LEUKOCYTE ADHESION AND FUNCTION*



Assistant Commissioner for Patents
Washington, D.C. 20231

## SUPPLEMENTAL APPEAL BRIEF

Sir:

Supplemental to the Appeal Brief filed June 19, 2000, and the Reply to the Examiner's answer filed March 16, 2001, Appellants bring the attention of the Board to a recent decision by the Federal Circuit Court of Appeals that is believed to have relevance to the Board's decision on the present case on appeal.

**(8) ARGUMENTS**

**(i) Rejections Under 35 U.S.C. § 112, first paragraph**

*Amgen, Inc. v. Hoechst Marion Roussel, Inc. and Transkaryotic Therapies, Inc. (C.A.F.C. 01-1191-1218)*

This decision was the appeal of a lengthy district court ruling on validity, infringement, and enforceability of five Amgen patents relating to production of erythropoietin (EPO), a hormone that controls formation of red blood cells. Amgen's EPO is

sold under the brand name EPOGEN®. The Federal Circuit upheld the lower court's claim construction and its decision that the claims comply with the written description and enablement requirements of 35 U.S.C. § 112.

In this case, Amgen described and enabled at least one way of obtaining EPO purified from mammalian cells in culture: the genetic manipulation of CHO and COS-1 cells, followed by purification techniques that were described and known in the art. Finally, the court also accepted testimony indicating that an ordinary skilled artisan would infer from the COS-1 (monkey) and CHO cell examples that similar outcomes could be expected from other mammalian cells since all mammalian cells produce and secrete hormones like EPO by means of the same fundamental processes. The court found that Amgen sufficiently met its burden for proving enablement, and that HMR's assertion that the Amgen disclosure was non-enabling for transformation of all mammalian or vertebrate cells or the production of human EPO was unfounded.

One question that arose out of these proceedings was whether or not Amgen's disclosure of one means of producing synthetic EPO in mammalian cells, namely exogenous DNA expression, entitles it to claim all EPO produced by mammalian cells in culture, or all cultures vertebrate cells that produce EPO. The district court in this case found that "the specification need teach only one mode of making and using a claimed composition." *Amgen, Inc v. Hoechst Marion Roussel, Inc* 126 F.Supp.2d 69, 160, 57 USPQ 2d 1449, 1515 (D.Mass.2001).

Although it has been argued that all candidates of a genus must be described in detail (*Regents of the Univeristy of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), the Court in this case found that "the specification's description of producing the claimed EPO in two species of vertebrate or mammalian cells adequately supports claims covering EPO made using the genus vertebrate or mammalian cells, [and] renders Eli Lilly listless in this case." *Amgen*, 126 F.Supp2d at 149, 57 USPQ2d at 1507. This decision has been extended to rule that adequate description of one species can satisfy the written description for the corresponding genus of compounds. Furthermore, the court ruled that in the event that the specification described and enabled various possible species and provided specific information on methods of use, description of one species would enable one of ordinary skill to practice the method using other members of the genus.

Another point emphasized by the Court regarded the necessityof providing proof in asserting that claims are non-enabled.

> "TKT cannot prevail simply by reasserting in a conclusory manner that Amgen's disclosure does not enable the transformation of all mammalian or vertebrate cells or the production of human EPO. The district court carefully considered these issues, finding in the end that TKT had not met its clear and convincing burden of proof. Finding no clear error in these factual determinations, and having been directed to no legal error committed by the trial court, we will not disturb its holding that the asserted patents are not invalid for failure to meet the enablement requirement of § 112 ¶ 1."

*Relevance to the Present Case on Appeal*

The findings of the above case support the Appellants' position that claims 1-6, 8, 11, and 12 are enabling for compounds other than Mac-1 antibodies in inhibiting integrin-mediated leukocyte adhesion. The Appellants have demonstrated the use of Mac-1 antibodiesto inhibit restenosis using an accepted animal model and have submitted evidence to support the use, and predictability of success, of other species within the claimed genus to inhibit integrin-mediated leukocyte adhesion such as a peptide. In view of the Court decision discussed above, Appellants have met the burden under 35 U.S.C. 112, with respect to compliance with the written description and enablement requirements for the claimed genus.

The Examiner has only made conclusory assertions that the present claims do not meet the requirements of section 112, first paragraph, without providing evidence or proof to establish a *prima facie* case of lack of enablement. Evidence has been submitted by the Appellants to rebut the Examiner's position. The Examiner has discounted the evidence by mere assertion, not by reference to any scientific or legal support. As was reiterated in the Amgen decision, absent clear and convincing evidence to establish a *prima facie* case of lack of enablement, this rejection is unfounded.

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## (9) SUMMARY AND CONCLUSION

For the foregoing reasons, Appellants submit that the claims 1-6, 8, 11, and 12 meet the legal standard for enablement and are patentable under 35 U.S.C. 112, first paragraph.

Respectfully submitted,

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I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being facsimile transmitted to the Board of Appeals, U.S. Patent and Trademark Office, Washington, D.C. 20231.

Jean Hicks

Date: February 21, 2003